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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,296	08/27/2001	Sithian Pandian	MBM1270	7256

7590 02/02/2004

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EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,296

Applicant(s)

PANDIAN ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 5-24 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-29 is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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NON-FINAL ACTION

1. The applicant's Response (filed 29 OCT 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 1-29** is/are pending with Claims 5-24 withdrawn from consideration. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

PRIORITY

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). **Please amend the specification to include a priority statement citing the earlier application(s) to which priority is desired.**

SEQUENCE Rules

3. This application fails to comply with the sequence rules. See the attached notice to comply with the sequence rules. See the bottom of page 19(*spec*).

See
1/28/03

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

CLAIM REJECTIONS UNDER 35 USC § 102/103

6. Claim(s) 1-4 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kellogg et al. (1990).

Claim 1 is drawn to an amplification probe comprising at least two regions of nucleic acid sequence including at first sequence complementary to a sequence on a selected primary probe and a second region which is to include a plurality of discretely labellable sequence units. Note, that the examiner has interpreted the phrase "discretely labellable sequence units" to mean : a sequence unit that is capable of, under appropriate conditions, becoming labeled via hybridization to a labeled detection probe. This interpretation is based on a reading of the specification pp. 17-19 wherein the applicants have explained what they intend by the phrase "amplification probe". It should also be noted that the limitations in claim 1 that are directed to the structure of the primary probe do not further limit the structure of the amplification probe, the product being claimed in Claim 1.

Kellogg et al teach a oligonucleotide SK19(+) which could function (i.e. is capable of performing) as an amplification probe as defined in Claims 1-4. For example, the probe SK19(+) is composed of 41 nucleotides. See attached Appendix A. The first 9 nucleotides at the 5' end of SK19 (+) can be said to be "complementary to a sequence on a selected primary probe". Next, the second region (i.e. the 32 nucleotides at the 3' end of SK19 (+)] can be said to include a plurality of (i.e. two) discretely labellable sequence units (i.e. the two 16-mer units at the 3' end of SK19(+)) as shown in attached Appendix A. Admittedly, Kellogg et al. do not teach using SK19(+) as recited in Claims 1-4 or as set forth by the examiner in above/ in attached Appendix A. However, please note that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. **If the prior art structure is capable of performing the intended use, then it meets the claim.** *In re Casey*, 152 USPQ 235 (CCPA

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1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Also note, that while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

7. Applicant's arguments with respect to the claimed invention have been fully and carefully and are deemed to be persuasive, however, a new ground of rejection has now been applied. See above.

CONCLUSION

8. Claim(s) 25-29 is/are allowable while Claim(s) 1-4 is/are rejected and/or objected to for the reason(s) set forth above.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

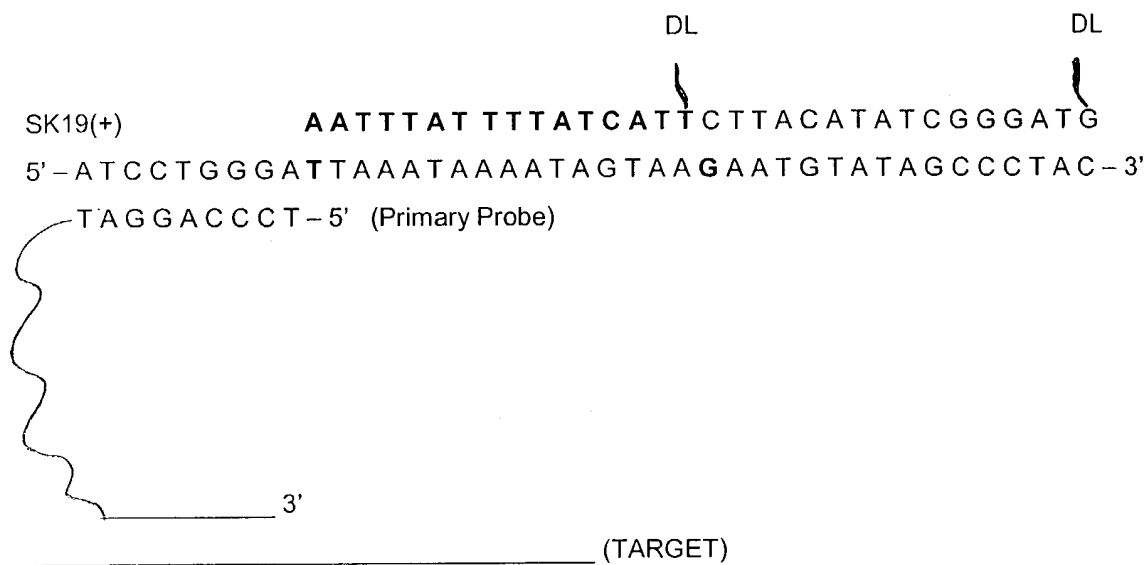


**ETHAN WHISENANT
PRIMARY EXAMINER**

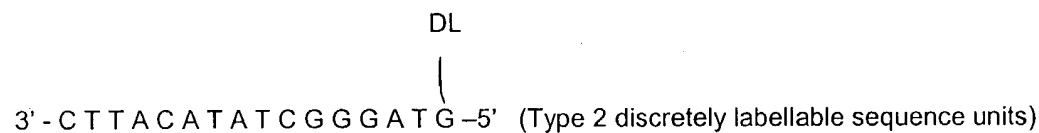
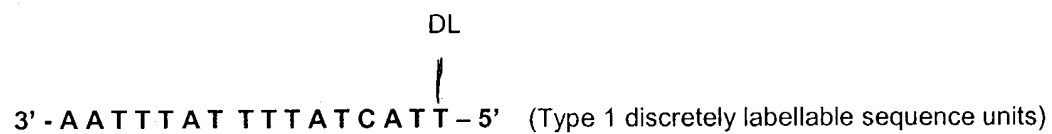
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APPENDIX A



The plurality of discretely labellable sequence units of more than one type (comprising 16 nucleotides each):



DL = DETECTABLE LABEL